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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,862	01/15/2004	Douglas H. Irish	DKP 0101 PUS1	4622
22045	7590	03/07/2006	EXAMINER	
BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075			AHMED, AAMER S	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/757,862

Applicant(s)

IRISH, DOUGLAS H.

Examiner

Aamer S. Ahmed

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-30 is/are allowed.
- 6) ☒ Claim(s) 1,6-10,12-15 and 18-21 is/are rejected.
- 7) ☐ Claim(s) 2-5,11,16 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01/15/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 8, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lessing, Jr. U.S. Patent Number 4,525,719. Lessing, Jr., teaches a belt-pack for securing a surgically implanted catheter comprising a pouch with front and back sides (col. 2 line 28-29) situated on a belt to be worn around the waist of the patient (col. 2 lines 18-19). The pouch has openings on its front and back sides providing access to the catheter system (col. 2 lines 33 and 38). The device can be used with peritoneal dialysis system, (col. 1 lines 10-11) and therefore, the internally implanted catheter would be connected to a fill-bag. Catheters used for these procedures are commonly made of a type of plastic.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lessing Jr., in view of Schuster 3,472,369.

Lessing Jr., as described above, teaches a belt pack for securing an implanted catheter, but fails to teach a peel away sealing mechanism for opening in the pouch.

Schuster teaches a similar plastic package for storing apparatus, wherein the contents of the pouch are maintained in a sterile environment by having a peel away seal disposed over the opening (see figure 5).

It would have been obvious to one having ordinary skill in the art at the time of the invention by applicant to incorporate the peel away sealing mechanism as taught by Schuster over the openings in the pouch of Lessing Jr., in order to prevent contamination of the contents therein, thereby preventing infection of the patient.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lessing Jr., in view of Vogel EP 0807449. Lessing Jr., as described above, teaches a belt pack for securing an implanted catheter, but fails to teach the use of an adhesive.

Vogel teaches a similar wearable apparatus to be used with dialysis catheters comprising a pouch made of plastic, having two openings and having an adhesive portion surrounding the rear opening of the pouch to attach to the patient's skin (see figure 1).

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It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Lessing Jr., by incorporating the adhesive as taught by Vogel in order to prevent movement of the pouch and trauma to the patient.

Claims 14,19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lessing Jr., in view of Miller et al 5,671,983. Lessing Jr., discloses the device as described above, but fails to teach hand-covering elements within the pouch.

Miller et al. teaches a storage bag with internally disposed hand covering elements (col. 1 lines 51-52).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to incorporate the use of hand covering mechanism to ensure a sterile environment for making the connection between the external tubing of the dialysis system and the implanted catheter. It would have been an obvious matter of design choice to color the pouch and the hand covering element differently as the applicant has not disclosed the altering the color solves any stated problem and it appears that the invention would perform equally well if the parts were the same color.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lessing Jr., in view of Miller et al as applied above to claim 14 above, and further in view of Vogel.

Lessing Jr., and Miller et al teach a belt pack and storage bag with hand covering elements, but fail to disclose an adhesive pouch.

Vogel, as described above teaches a similar wearable apparatus to be used with dialysis catheters comprising a pouch having an adhesive portion surrounding the rear opening of the pouch (see figure 1).

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It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Lessing Jr., and Miller et al, by incorporating the use of adhesive in order to prevent movement of the pouch and trauma to the patient.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lessing Jr., and Miller et al as applied to claim 14 above, and further in view of Bennes et al U.S. Patent Number 5,853,396. Lessing Jr., and Miller et al describe the device as described above in reference to claim 14, but fail to disclose a clamping mechanism to be applied to a catheter.

Bennes et al teaches a belt to be worn by patients receiving peritoneal dialysis comprising a pouch with front and back sections (col. 4 lines 24-26) with rear openings for receiving the implanted catheter. The catheter that is implanted into the patient's body is connected to a fill bag and drain bag through a Y-connections (col. 5 lines 6-9) and has a clamping means attached to one end (col. 2 lines 36-37).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Lessing Jr., and Miller et al by incorporating the clamping mechanism as taught by Bennes et al in order to prevent flow when the system is not in use.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lessing Jr., and Miller et al as applied to claim 14 above, and further in view of Schuster. Lessing Jr., and Miller et al describe the device as described above in reference to claim 14, but fail to disclose a peel away sealing mechanism for the openings in the pouch.

Schuster teaches a similar plastic package for storing items wherein the contents of the pouch are maintained in a sterile environment by having a peel away seal disposed over the openings.

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Lessing Jr., and Miller et al by incorporating the peel away seal as taught by Schuster in order to prevent contamination and potential infection of the patient.

Allowable Subject Matter

Claims 2-5, 11, 16 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 22-30 are allowed. None of the prior art of record teaches a peritoneal dialysis system comprising a user wearable device including a pouch with two openings wherein the connection made between the catheter and the fill-drain tube are connected within the pouch by external manipulation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-30 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-27 of U.S. Patent No. 6,682,507. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the elements and limitations in the instant application are recited in the issued patent.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

EP 335814 A2	ANASIS, PAUL JOHN
US 4551888 A	Beecher; William H.
US 5669884 A	Bennes; Solita M. et al.
US 20020165495 A1	Bird, John R. et al.
US 6645185 B2	Bird; John R. et al.
US 5352209 A	Bird; John R. et al.
US 4799923 A	Campbell; Myrna
US 5468229 A	Chandler; Janice
US 5776105 A	Corn; Stephen B.
US 5336195 A	Daneshvar; Yousef
US 6270485 B1	Ekey; Barbara Norton
US 5980499 A	Ekey; Barbara Norton
US 4955867 A	Endo; Walter Y.
US 6027489 A	Galato; Raffaele
US 6234991 B1	Gorsuch; Reynolds G.
US 5980481 A	Gorsuch; Reynolds G.
US 4569348 A	Hasslinger; Russell
US 4088136 A	Hasslinger; Russell et al.
US 20050033241 A1	Hottinger, Molly
US 5624403 A	Jaquith; Jerrie L.
US 5037397 A	Kalt; Glenda G. et al.
US 5685859 A	Kornerup; Niels
US 5688248 A	Lessing, Jr.; Kenneth C.
US 6579268 B1	Loining; Michelle J.
US 5758660 A	Lokken; Oddvin
US 4767405 A	Lokken; Oddvin
US 6544232 B1	McDaniel; Gladys P.
US 5496282 A	Militzer; George G. et al.
US 4582508 A	Pavelka; Wilma F.
US 6610032 B1	Prody; MaryAnn Robinson
US 3472369 A	SCHUSTER SAMUEL J
US 4596560 A	Simpson; Mary

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US 6126639 A	Sutherland; Joanne M. et al.
US 5643233 A	Turner; Nancy F.
US 5728070 A	Walker, deceased; Herbert B. et al.
US D437410 S	Watson; Paul L. et al.
US 6152915 A	Watson; Paul L. et al.

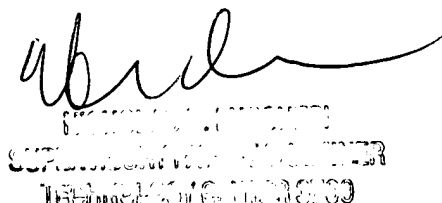
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A. Ahmed



Handwritten signature and official stamp of the examiner, Aamer S. Ahmed, dated 11/16/09.

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